REMARKS

Reconsideration of the allowability of the present application in view of the above claim amendments and the following remarks is requested respectfully.

Discussion of the Claims

In his Action, the Examiner acted upon Claims 1 to 5, 20, 22 to 40, 45 to 51, 53, and 54 of the application, Claims 41 to 44 having been withdrawn previously from further consideration as being directed to non-elected species and Claims 6 to 19, 21, and 52 having been cancelled.

In the present Reply, Claims 3, 22, 41 to 44, 53, and 54 have been cancelled without prejudice. Claims 1, 4, 5, 23, 24, 28 to 30, 35, and 47 have been amended. Claims 55 to 57 have been added.

The claims pending presently are Claims 1, 2, 4, 5, 20, 23 to 40, 45 to 51, and 55 to 57.

Discussion of the Amendments

The current claims include two independent "formulation" claims, namely Claims 1 and 47. Claim 1 has been amended to provide antecedent basis for the phrase "the core", which is used in various dependent claims, and to clarify that the core has thereon a rate-controlling membrane coating. Claim 47 has been amended to be consistent with Claim 1 in the use of the phrase "the core". Support for these amendments is found in Claim 3, now cancelled.

Claims 1 and 47 have been amended also to define the active agent as being fluvoxamine or a pharmaceutically-acceptable salt thereof. Support for this is found in Claims 1 and 47 as they were prior to amendment.

Claims 23, 24, and 28 to 30 have been amended and Claims 55 to 57 have been added to define the formulation as one in which the rate-controlling membrane coating is present in an mount such that it contributes to the particle a weight gain of from about 4% to about 15% of the weight of the core and is formed from a lacquer substance comprising ammonio methacrylate copolymer. Claim 56 further defines the formulation as one in which the weight gain contributed is 4%, 6%, 8%, 10%, 12%, or 15% of the weight of the core. Support for the above amendments and for Claim 55 to 57 is found in the application at, for example, page 27, and in Claims 5 and 47.

Claims 4 and 35 have been amended to depend from Claim 2. Prior to amendment, these claims depended from now cancelled Claim 3. The recitations of Claim 3 are incorporated into Claim 2 by virtue of the amendment to Claim 1 from which Claim 2 depends.

Claims 3, 22, 41 to 44, 53, and 54 have been cancelled without prejudice.

An amendment of an editorial nature has been made to Claim 5.

Applicants submit that a new search does not need to be conducted and the amendments place the claims in better form for consideration on appeal. Applicants request, therefore, that the above amendments be entered.

Discussion of the Examiner's Section 102(e) Rejection

The Examiner rejected Claim 54 under Section 102(e) as being anticipated by U.S. Patent No. 5,958,458 Norling et al. This rejection has been rendered moot by the cancellation of this claim.

Discussion of the Examiner's Section 103 Rejection

The Examiner has rejected Claims 1 to 5, 20, 22 to 40, 45 to 51, 53, and 54 under Section 103(a) as being unpatentable over the disclosure of U.S. Patent No. 5,958,458 to Norling et al. in view of U.S. Patent No. 6,183,780 to van Balken et al.

The Examiner's rejection is traversed respectfully. To establish a *prima facie* case of obviousness, the Examiner must show that one skilled in the art would have expected that the invention would work for its intended purposes. MPEP § 2143. Applicants submit respectfully that the Examiner has failed to establish a *prima facie* case of obviousness.

There is nothing in the combined disclosures of the cited art to lead one skilled in the art to have a reasonable expectation the fluxoamine, when substituted for the anti-depressants used in the formulations disclosed by Norling et al., would be released in the release profile specified by the claims. The Examiner argues that there is such an expectancy since Norling et al. discloses formulations which are "identical" to those claimed. This, however, is not the case as Norling does not disclose the use of fluvoxamine. Instead, it discloses only the use of anti-depressants which are imipramine, nortriptyline or pririptylene [sic] (protriptylene) and discloses specifically only formulations comprising theophylline and the release profiles achieved by such formulations. Theophylline is not chemically similar to fluvoxamine, either in property or in structure. Different compounds are expected to have different release properties. Accordingly, one skilled in the art would not have assumed that, simply because Norling et al. discloses that theophylline is released from the formulations therein in a certain profile, fluvoxamine, when substituted for theophylline, would also be released in the same profile.

Further, Claims 23, 24, 28, 29, 30, and 55 to 58 recite specific release

profiles and recite that the membrane coating is present in defined amounts and comprises ammonio methacrylate copolymer. Nothing in the cited art would give rise to an expectancy that particles coated with a membrane present in the specified amounts and comprising ammonio methacrylate copolymer would allow for release of SSRIs (or their respective salts) in the profiles recited.

For the reasons recited above, applicants request respectfully that the Examiner withdraw his Section 103 rejection.

Discussion of the Examiner's Section 112 Rejection

The Examiner has rejected Claims 23, 24, and 28 to 30 under the enablement requirement of Section 112, first paragraph, because the Examiner does not consider the claims to be enabled with respect to formulations other than those in which the rate-controlling membrane coating comprises Eudragit® (ammonio methacrylate copolymer) and is present in an amount such that it contributes to the particle a weight gain of 4%, 6%, 8%, 10%, 12%, or 15% of the weight of the core. According to the Examiner, the application has shown only that those formulations exhibit the release profile specified by the claims.

Applicants have amended Claims 23, 24, and 28 to 30 to define the membrane coating as being present in an amount such that it contributes to the particle a weight gain of from about 4% to about 15% of the weight of the core and is formed from a lacquer substance comprising ammonio methacrylate copolymer. It is believed that this amendment will overcome the Examiner's rejection. Although the above range encompasses amounts other than the specified 4%, 6%, 8%, 10%, 12%, or 15% amounts, it is intuitive that, if a formulation which comprises a membrane coating which is present in those amounts exhibits the specified release profile, formulations which comprise a membrane coating which is present in amounts in between the above specified amounts must exhibit the specified release profile as well.

In any event, it is noted that Claim 56 has been added to define the formulations as comprising a membrane coating which is present in an amount such that it contributes to the particle a weight gain of 4%, 6%, 8%, 10%, 12%, or 15% of the weight of the core and as being formed from a lacquer substance comprising ammonio methacrylate copolymer.

Discussion of the Examiner's Election of Species Requirement

Applicants advise that new Claims 55 to 57 are readable on the elected species.

Conclusion

For the reasons expressed above, applicants request respectfully that the Examiner reconsider and withdraw his rejections. An early and favorable allowance is requested respectfully.

The Examiner is invited to telephone the undersigned to discuss matters that the Examiner believes may be relevant to placing the application in condition for allowance.

Respectfully submitted,

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